

August 21, 2002

Dr. Anne P. LeHuray
Rubber and Plastic Additive (RAPA) Panel
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209

Dear Dr. LeHuray:

We have conducted a review of the Thiuram category submitted by The American Chemistry Council's RAPA Panel as part of their commitment made under the HPV Challenge Program.

Our analysis focused on the overall approach including the category definition and description and a review of the submitted study summaries. We have concluded that while the category proposal may be feasible and believe that the data submitted for tetramethyl thiuram disulfide could be extrapolated to tetraethyl thiuram disulfide, we are unable to continue evaluation for the following reasons:

The test plan for the Thiuram category states that there are adequate studies for all health and ecological endpoints for both chemicals except for a reproductive toxicity study for tetraethyl thiuram disulfide. Many of the summaries, however, have insufficient information to independently assess the quality of the underlying studies. In addition, some studies referenced in the test plan do not have summaries (studies on acute toxicity to invertebrates and acute algal toxicity are missing for tetraethyl thiuram disulfide).

Please note that all submitted summaries need to be in English. However, some of the submitted summaries were in Spanish. In addition, in several instances multiple summaries were submitted for what appears to be a single study (in both the health effects and ecological effects sections). This hampers weight-of-evidence considerations when reviewing many individually inadequate summaries to conclude whether or not the endpoint has been addressed.

For health effects, several FIFRA guideline studies are available on tetramethyl thiuram disulfide for all endpoints, all were inadequately summarized and poorly documented, and not enough information was available to evaluate their adequacy.

Similarly, for ecological effects, for tetramethyl thiuram disulfide, 18 inadequate summaries of acute toxicity to fish were included (two of these may be more appropriately classified as chronic studies). Six summaries for acute toxicity to invertebrates are on what appear to be four studies and six summaries for algal toxicity studies cover five studies. These summaries are inadequate because they lack critical elements required to assess data adequacy and also because of inconsistencies among toxicity values. The available data do not suggest that the endpoints would be adequately supported by weight-of-evidence considerations.

We strongly recommend that the sponsor follow the guidance document for completing the robust summaries available at <http://www.epa.gov/opptintr/chemrtk/guidocs.htm>.

I encourage the RAPA Panel to take the necessary steps to enhance the submission. We are prepared to proceed to final data adequacy determinations as soon as we get your response.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

Sincerely,

-S-

Oscar Hernandez